IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
NEWARK DIVISION

VICKY WATKINS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA LP, Defendants.	)	CASE NO.: ________________ **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff, VICKY WATKINS, for her Complaint alleges as follows:

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff VICKY WATKINS (hereinafter "Plaintiff") as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of the proton pump inhibiting ("PPI") drug known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient herein collectively referred to as "NEXIUM".

PARTIES

Plaintiff

2. At all times referenced herein, Plaintiff VICKY WATKINS was and is a citizen of the State of Tennessee.

Defendants

AstraZeneca Pharmaceuticals LP

3. Defendant AstraZeneca Pharmaceuticals LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

4. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling NEXIUM products.

5. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's state of residency.

6. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in Plaintiff's state of residency and derived substantial revenue from such business.

7. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States of America, and Plaintiff's state of residency in particular.

8. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications ("NDAs") for the following forms of NEXIUM:

a. Delayed-Release Capsule Pellets (20 mg and 40 mg) , with NDA # 021153, approved on 2/20/2001;

b. Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006;

c. Delayed-Release Oral Suspension Packets (10MG), with NDA number 022101, approved on 02/27/2008; and

d. Injection (20MG VIAL, 40MG VIAL), with NDA number 022101, approved on 03/31/2005.

AstraZeneca LP

9. At all times relevant hereto, Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling NEXIUM products.

10. Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

11. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's state of residency.

12. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in Plaintiff's state of residency and derived substantial revenue from such business.

13. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, and Plaintiff's state of residency in particular.

AstraZeneca Pharmaceuticals LP & AstraZeneca LP's Unity of Interest

14. Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP shall herein be collectively referred to as "Defendants" or "AstraZeneca."

15. On information and belief, at all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority of each other Defendant and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

16. Moreover, each Defendant was the agent and employee of each other Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant's actual and implied permission, consent, authorization, and approval. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injuries, losses and damages.

JURISDICTION AND VENUE

17. This Court has jurisdiction pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

18. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(b) because, at all times material hereto, Defendants conducted substantial business in this district.

FACTUAL BACKGROUND

Proton Pump Inhibitors Generally

19. Proton pump inhibitors ("PPI") are one of the most commonly prescribed medications in the United States to treat conditions such as:

a. Gastroesophageal reflux disease (GERD)

b. Dyspepsia

c. Acid peptic disease

d. Zollinger-Ellison syndrome

e. Acid reflux, and

f. Peptic or stomach ulcers.

20. In 2013, more than 15 million Americans used prescription PPIs, costing more than $10 billion. Of these prescriptions, however, it has been estimated that between 25% and 70% of them have no appropriate indication.

21. AstraZeneca sold NEXIUM with National Drug Code (NDC) numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040.

22. NEXIUM is AstraZeneca's largest-selling drug and, in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded $5.7 billion dollars. In 2008, Nexium sales exceeded $5.2 billion dollars.

23. NEXIUM (esomeprazole magnesium) is a PPI that works by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach, reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

Dangers Associated with PPIs

24. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this product including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

25. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA in association with ingestion of Nexium and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports,

clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of several types of kidney and related injuries in patients that had ingested NEXIUM, including:

a. Acute Interstitial Nephritis (AIN),

b. Chronic Kidney Disease (CKD),

c. Renal/Kidney Failure,

d. Acute Kidney Injury (AKI), and

e. Clostridium difficile.

26. These reports of numerous injuries put Defendants on notice as to the excessive risks of injuries related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

Acute Interstitial Nephritis (AIN) Dangers Associated with PPIs

27. Acute Interstitial Nephritis (AIN) is the Inflammation of the Tubes and Tissues of the Kidneys. The most common symptoms are fatigue, nausea and weakness. AIN-related symptoms can begin as early as one week following PPI ingestion.

28. The risk of AIN among PPI users was first raised in 1992. Five years later, an additional study raised concerns. By 2011, the World Health organization adverse drug reaction report included nearly 500 cases of AIN as of July 2011.

29. Between 2004 and 2007 at least three additional studies confirmed AIN related to PPI usage. More recent studies indicate that those using PPIs such as Nexium are at a three times greater risk than the general population to suffer AIN.

30. On or about October 30, 2014, the FDA notified Defendants that the FDA determined that PPIs (and all forms for NEXIUM, specifically) pose additional risks not previously disclosed.[1]

31. On December 19, 2014, the labeling for PPIs was updated to include a warning about AIN. The new label added a (never-before-included) section about AIN that read, in the relevant part, that AIN "may occur at any point during PPI therapy." [2]

32. Among others, the following medical studies support the fact that there is an association between PPIs, including NEXIUM, and AIN:

a. Ruffenach, Stephen J., Mark S. Siskind, and Yeong-Hau H. Lien, *Acute interstitial nephritis due to omeprazole*. The American journal of medicine 93, no. 4 (1992): 472-473.

b. Badov, David, Greg Perry, John Lambert, and John Dowling, *Acute interstitial nephritis secondary to omeprazole*, Nephrology Dialysis Transplantation 12, no. 11 (1997): 2414-2416, *available at* http://ndt.oxfordjournals.org/content/12/11/2414.short .

c. Torpey, Nicholas, Tim Barker, and Calum Ross, *Drug-induced tubulo-interstitial nephritis secondary to proton pump inhibitors: experience from a single UK renal unit*, Nephrology Dialysis Transplantation 19, no. 6 (2004): 1441-1446, *available at* http://ndt.oxfordjournals.org/content/19/6/1441.short .

d. Geevasinga, Nimeshan et al., *Proton Pump Inhibitors and Acute Interstitial Nephritis*, Clinical Gastroenterology and Hepatology , Volume 4 , Issue 5 , 597 – 604, *available at* http://www.cghjournal.org/article/S1542-3565(05)01092-X/abstract?cc=y=.

e. Harmark, Linda, Hans E. Van Der Wiel, Mark C. H. De Groot, and A. C. Van Grootheest, 2007, *Proton Pump Inhibitor-Induced Acute Interstitial Nephritis*, British Journal Of Clinical Pharmacology 64 (6): 819-823,

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[1] *See* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/021153Orig1s050,021957Orig1s017,022101Orig1s014ltr.pdf

[2] *See* December 19, 2014 label at 1 & 6, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022101s014021957s017021153s050lbl.pdf.

available at http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2125.2007.02927.x/full .

f. K. Sampathkumar, A. Abraham. 2013, *Acute Interstitial Nephritis Due To Proton Pump Inhibitors*, Indian Journal Of Nephrology 23 (4): 304, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3741979/.

33. Even the current warning of AIN is far from complete, lacking the necessary force to give patients and theaters the proper information needed to make an informed decision about whether to start a drug regimen with such potential dire consequences.

34. If left untreated, AIN can lead to Chronic Kidney Disease (CKD) and kidney failure.

Chronic Kidney Disease (CKD) Dangers Associated with PPIs

35. CKD is the gradual loss of kidney function. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body.

36. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

37. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often key to avoiding the most negative outcomes.

38. CKD is associated with a substantially increased risk of death and cardiovascular events.

39. Studies have shown the *long term* use of PPIs was independently associated with a 20% to 50% higher risk of CKD, after adjusting for several potential confounding variables,

including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications.

40. In at least one study, the use of PPIs for *any period of time* was shown to increase the risk of CKD by 10%.

41. As a whole, patients with renal disease are nearly twice as likely to have been exposed to PPIs compared to those without renal disease.

42. Among others, the following medical studies support the fact that there is an association between PPIs, including NEXIUM, and CKD:

a. Brewster, U. C., and M. A. Perazella, *Proton pump inhibitors and the kidney: critical*, Clinical Nephrology 68, no. 2 (2007): 65-72, *available at* https://www.researchgate.net/profile/Mark_Perazella/publication/6117052_Proton_pump_inhibitors_and_the_kidney_Critical_review/links/5540b3b40cf2b7904369ac54.pdf .

b. Tony Antoniou, David N. Juurlink. 2015, *Proton Pump Inhibitors And The Risk Of Acute Kidney Injury In Older Patients: A Population-Based Cohort Study*, CMAJ Open 3 (2): E166, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/ (three times Greater Risk of AIN with PPI).

c. Lazarus B, Chen Y, Wilson FP, et al., *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*., JAMA Intern Med. 2016;176(2):. doi:10.1001/jamainternmed.2015.7193, *available at* https://archinte.jamanetwork.com/article.aspx?articleid=2481157&version=meter+at+null&module=meter-Links&pgtype=Blogs&contentId=&mediaId=%25%25ADID%25%25&referrer=&priority=true&action=click&contentCollection=meter-links-click (20-50% increased risk of Chronic Kidney Disease).

43. Currently, NEXIUM lacks any warning of CKD.

Acute Kidney Injury (AKI) Dangers Associated with PPIs

44. Studies indicate that those using PPIs such as Nexium are at greater than a 2.5 times greater risk than the general population to suffer AKI. The AKIs occurred with 120 days of the patients staring the PPIs.

45. Studies also indicated that those who develop AIN are at significant risk of AKI even though they may not be an obvious case kidney dysfunction.

46. Among others, the following medical studies support the fact that there is an association between PPIs, including NEXIUM, and AKI:

a. Brewster, U. C., and M. A. Perazella, *Proton pump inhibitors and the kidney: critical*, Clinical Nephrology 68, no. 2 (2007): 65-72, *available at* https://www.researchgate.net/profile/Mark_Perazella/publication/6117052_Proton_pump_inhibitors_and_the_kidney_Critical_review/links/5540b3b40cf2b7904369ac54.pdf .

b. Klepser, Donald, Dean Collier, and Gary Cochran. 2013, *Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case–Control Study*, BMC Nephrology 14 (1): 1, *available at* http://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-14-150.

c. Tony Antoniou, David N. Juurlink. 2015, *Proton Pump Inhibitors And The Risk Of Acute Kidney Injury In Older Patients: A Population-Based Cohort Study*, CMAJ Open 3 (2): E166, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/ (three times Greater Risk of AIN with PPI).

d. Yen-Chun Peng, Chia-Hung Kao. 2016, *Association Between The Use Of Proton Pump Inhibitors And The Risk Of ESRD In Renal Diseases: A Population-Based, Case-Control Study*, Medicine 95 (15), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4839840/.

47. Currently, NEXIUM lacks any warning of AKI.

Safer Alternatives

48. Despite the fact that Nexium and other PPIs lead to an increased risk of the numerous injuries outlined herein, numerous safer alternatives are available.

49. Such safer alternative treatments include but are not limited to:

a. the use of over-the-counter calcium carbonate remedies tablets that have been available since the 1930s, such as Maalox and Tums, and/or

b. the use of histamine H2-receptor antagonists (also known as H2 blockers) that were developed in the late 1960s. H2 blockers act to prevent the production of stomach acid, and work more quickly than PPI. Examples of H2 blockers are Zantac, Pepcid, and Tagamet.

50. Even though these safer alternatives at all relevant times existed, the sale of PPIs such as Nexium skyrocketed as the same time that the safer alternatives, namely the as H2 blockers, plummeted.

51. This is true despite the fact that higher kidney injury risks are specific to PPI medications. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with such renal injuries.

Allegations Common to All Causes of Action

52. Defendants knew or should have known about the correlation between the use of Nexium and the significantly increased risk of CKD, AKI, and renal impairment. Yet Defendants failed to adequately warn against these negative effects and risks associated with NEXIUM.

53. In omitting, concealing, and inadequately providing critical safety information regarding the use of NEXIUM to Plaintiff and Plaintiff's doctors in order to induce its purchase, prescription and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff and Plaintiff's doctors. This conduct is fraudulent, unfair, and unlawful.

54. Despite clear knowledge that NEXIUM causes a significantly increased risk of CKD, AKI, and renal impairment, Defendants continue to market and sell NEXIUM without warning consumers or healthcare providers of these significant risks.

Plaintiff's Use of Nexium and Resulting Harm

55. Plaintiff VICKY WATKINS is and was at all times alleged herein a citizen of the State of Tennessee.

56. Plaintiff VICKY WATKINS was prescribed Nexium on numerous occasions, including but not limited to, in or about October 2012 through March 2013. Plaintiff VICKY WATKINS ingested Nexium as prescribed by her doctor.

57. Plaintiff VICKY WATKINS read and followed the directions regarding the use of Nexium and would not have used Nexium had she been properly apprised of the risks associated with the use of Nexium.

58. Plaintiff VICKY WATKINS suffered Chronic Kidney Disease (CKD) while taking Nexium as prescribed in or about March 2013.

TOLLING OF THE STATUTE OF LIMITATIONS

59. Defendants, at all relevant times, knew or should have known of the problems and defects with Nexium products, and the falsity and misleading nature of Defendants' statements, representations and warranties with respect to Nexium products. Defendants concealed and failed to notify Plaintiff and the public of such defects.

60. Any applicable statute of limitation has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is ongoing.

COUNT I
PRODUCT LIABILITY ACT — DEFECTIVE DESIGN
(N.J.S.A. 2A:58C-1, *et seq.*)

61. Plaintiff restates the allegations set forth above as if fully rewritten herein.

62. NEXIUM is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

63. At all times material to this action, NEXIUM was expected to reach, and did reach, consumers in Plaintiff's home state and throughout the United States, including receipt by Plaintiff, without substantial change in the condition in which it was sold.

64. At all times material to this action, NEXIUM was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, NEXIUM contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing CKD and other serious injuries and side effects;

b. When placed in the stream of commerce, NEXIUM was defective in design and formulation, making the use of NEXIUM more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat GERD and other stomach-acid-related ailments;

c. The design defects of NEXIUM existed before it left the control of Defendants;

d. NEXIUM was insufficiently and inadequately tested;

e. NEXIUM caused harmful side effects that outweighed any potential utility; and

f. NEXIUM was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

65. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT II
PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A:58C-1, *et seq.*)

66. Plaintiff restates the allegations set forth above as if fully rewritten herein.

67. NEXIUM was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing CKD and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for

GERD and other stomach-acid-related ailments. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq.*

68. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

69. Plaintiff was prescribed and used the subject product for its intended purpose.

70. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

71. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

72. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

73. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

74. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to: Acute Interstitial Nephritis (AIN), Chronic Kidney Disease (CKD), Renal/Kidney Failure, Acute Kidney Injury

(AKI), and Clostridium difficile.

75. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants

76. Defendants had a continuing duty to warn Plaintiff of the dangers associated with NEXIUM.

77. Had Plaintiff received adequate warnings regarding the risks of NEXIUM, she would not have used it and/or chosen a different course of treatment.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT III
BREACH OF EXPRESS WARRANTY

78. Plaintiff restates the allegations set forth above as if fully rewritten herein.

79. Defendants expressly represented to Plaintiff, other consumers, and the medical community that NEXIUM was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

80. NEXIUM does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to, developing CKD and other serious injuries and side effects.

81. At the time of the making of the express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to

an express warranty of Defendants.

82. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

83. At all relevant times NEXIUM did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

84. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IV
PUNITIVE DAMAGES ALLEGATIONS
(N.J.S.A. 2A:58C-5c)

85. Plaintiff restates the allegations set forth above as if fully rewritten herein.

86. Despite the holding of *McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), numerous courts around the country, and in this District specifically, have found that punitive damages are appropriate under N.J. Stat. Ann. § 2A:58C-5c subsequent to *Wyeth v. Levine*, 555 U.S. 555 (2009). *See, e.g.*, *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009) ("The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth.*").

87. The wrongs done by Defendants were aggravated by malice, fraud, and grossly

negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and her healthcare providers.

88. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

89. Plaintiff therefore asserts claims for exemplary damages.

90. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

91. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of NEXIUM. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of NEXIUM, and intentionally downplayed the type, nature, and extent of the adverse side effects

of ingesting NEXIUM, despite their knowledge and awareness of these serious side effects and risks.

92. Defendants had knowledge of, and were in possession of evidence demonstrating that NEXIUM caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of NEXIUM.

93. Although Defendants knew or recklessly disregarded the fact that NEXIUM causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute NEXIUM to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

94. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing NEXIUM and consumers from purchasing and ingesting NEXIUM, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming NEXIUM.

95. Defendants knew of NEXIUM's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by NEXIUM.

96. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other NEXIUM users and for the primary purpose of increasing Defendants' profits from the sale and distribution of NEXIUM. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against

Defendants in an amount appropriate to punish and make an example out of Defendants.

97. Prior to the manufacture, sale, and distribution of NEXIUM, Defendants knew that the drug was in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of NEXIUM to risk of injury or death.

98. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in NEXIUM and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of NEXIUM knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

99. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment against all Defendants and award additional relief as follows:

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;

2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;

3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

4. Punitive damages for the acts complained of herein in an amount to be determined by a jury;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest pursuant to Title 6 Delaware Code;

7. For the costs of suit;

8. For post-judgment interest; and

9. For such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff demands a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

SEEGER WEISS LLP

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